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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO W 09/092,374 06/05/98 SWEEZER **EXAMINER** QM12/0425 MAYNARD, J JAMES M. HESLIN, JENS E. HOEKENDIJK JEFFRY J. GRAINGER, MARK D. BARRISH ART UNIT PAPER NUMBER TOWNSEND AND TOWNSEND AND CREW LLP 3763 TWO EMBARCADERO CENTER, 8TH FLOOR 16 SAN FRANCISCO CA 94111-3834 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

04/25/01

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		Application No.	Applicant(s)
Office Action Summary		09/092,374	SWEEZER ET AL.
		Examiner	Art Unit
		Jennifer J Maynard	3763
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply sepecified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status			
1)⊠	Responsive to communication(s) filed on 05 I	February 2001 .	
2a) <u></u> □	This action is FINAL. 2b)⊠ Th	nis action is non-final.	
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
4)⊠	4) Claim(s) <u>55-58</u> is/are pending in the application.		
	4a) Of the above claim(s) <u>50-54</u> is/are withdrawn from consideration.		
5)	Claim(s) is/are allowed.		
6)⊠	☑ Claim(s) <u>55-58</u> is/are rejected.		
7)	Claim(s) is/are objected to.		
8)□	8) Claims are subject to restriction and/or election requirement.		
Application Papers			
9) The specification is objected to by the Examiner.			
10)	0) The drawing(s) filed on is/are objected to by the Examiner.		
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved.			
12)	12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of:			
ŕ	1. Certified copies of the priority documents have been received.		
	2. Certified copies of the priority documents have been received in Application No		
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>			
14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
Attachment(s)			
15) Notice of References Cited (PTO-892)  18) Interview Summary (PTO-413) Paper No(s)  19) Notice of Informal Patent Application (PTO-152)  17) Information Disclosure Statement(s) (PTO-1449) Paper No(s)  20) Other:			

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#### **DETAILED ACTION**

### **Priority**

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged and granted.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al.-'016.

Valley et al. discloses an aortic balloon catheter which is adapted to be inserted into the patient's arterial system and then advanced into the ascending aorta where the occluding member is expanded to occlude the aorta. The catheter can be used to introduce a cardioplegic agent and to supply oxygenated blood to the body from a bypass system. The aortic catheter is introduced under fluoroscopic guidance over a suitable guidewire.

Valley et al. fails to disclose the catheter being inserted through the subclavian artery.

Since the subclavian artery is in direct communication with the aortic arch, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have introduced the aortic balloon catheter taught by Valley et al. into the ascending aorta via the

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subclavian artery, as it is merely an alternative site of introduction. Valley et al. inserts the catheter into the femoral artery through a site in the pelvic area which then threaded to the aortic arch and subsequently located within the ascending aorta. The subclavian artery is located in the area of the clavicle and shoulder joint which is in closer proximity to the aortic arch and would require a lesser amount of distance to be traversed by the catheter thus lessening trauma to the artery during the threading process. Additionally since the subclavian artery is a smaller artery relative to the femoral artery it would inherently result in less blood loss.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Valley et al.-'016 in view of Peters-'170.

Valley et al. discloses the method as claimed with the exception of the step of occluding the vena cava during the step of removing blood.

Peters discloses a method for intraluminally inducing cardioplegic arrest wherein a catheter (11) with a pair of inflatable balloons (14 and 15) are positioned within each of the superior and inferior vena cavae (16 and 17), so as to occlude blood flow therethrough.

It would have been obvious to have modified the steps taught by Valley et al.-'016 with the step of occluding the superior and inferior vena cavae, as it facilitates efficient pumping during the by-pass procedure.

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#### Conclusion

Any inquiry concerning this communication should be directed to Jennifer Maynard at telephone number (703) 305-1356. Examiner Maynard can normally be reached at the above number from Mon-Fri. 7:30 A.M. to 5:00 P.M.

If attempts to reach Examiner Maynard are unsuccessful, the Examiner's Richard Seidel can be reached at 703-308-5115. The fax number for this unit is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at 703-308-0858.

J Maynard mumud

April 20, 2001

GLENN K. DAWSON PRIMARY EXAMINER